



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OPPTS/OPP/RD/TRB/PRODUCT CHEMISTRY TEAM

WASHINGTON, D.C. 20460

DATE: 11/MAY/2001

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]**

DP BARCODE No.: D273170

REG./File Symbol No.: 279-GEUR

PRODUCT NAME: Aim 2EC

COMPANY: FMC Corp Agricultural Products Group

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Product Chemistry Team
Technical Review Branch/RD (7505C)

TO: Joanne Miller/Dianne Morgan PM 23
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INTRODUCTION

FMC Corp Agricultural Products Group has submitted two new end-use formulations for their technical herbicide, carfentrazone-ethyl technical (Reg. No. 279-3181, 90%), Aim 2 EC and Aim 2 EW, (279-GEUR and 279-GEUE, respectively) in a letter dated 1/24/01. FMC claims that the new formulations will more readily combine with other pesticides used in tank mixes. Food and feed crops include uses on corn, sorghum, rice, soybeans, wheat, barley, oats, etc.

FMC stated in their 1/24/01 letter that Aim 2 EC and Aim 2 EW are to be used on the same crops and at the same use rates as Aim 40DF (Carfentrazone-ethyl 40DF, Reg. No. 279-3194). FMC cited data submitted previously for Carfentrazone-ethyl and has submitted additional data (MRID 453252-01 for the Aim 2 EC and MRID 453143-01 for the Aim 2 EW), a "cite-all" data matrix intended for both Aim 2 EC and Aim 2 EW, a label (dated 1/23/01) and later a revised proposed 4/20/01 label.

The subject of this review is Aim 2 EC, Reg. No. 279-GEUR, which (according to EPA calculations), contains 22.1% Carfentrazone-ethyl ai, formulated using Carfentrazone-ethyl (Reg. No. 279-3181, 90 %).

Aim 2 EC is also referred to in this submission (FMC Report P-3471, Vol. 2 of 10) as Carfentrazone-ethyl 240 g/l EC, G1159-141, FMC 6023, Carfentrazone-Ethyl-Ethyl, and as "Carfentrazone-ethyl 240 EC" in box 3 of the proposed 11/13/00 CSF, Reg. No. 279-GEUR.

CSFs proposed for Aim 2 EC and Aim 2 EW are both dated 11/13/00.

FINDINGS:

- The labels proposed 1/23/01 for Aim 2 EC and Aim 2 EW contained an incorrect value for the % Carfentrazone-ethyl. Following a conversation with the reviewer, Ms. Eugenia McAndrew and Dr. Callista Chukwunenye of FMC, updated (more nearly correct) labels for Aim 2EC and Aim 2EW, dated 4/20/01, were FAXed and subsequently sent 4/23/01 to EPA.
- The flash point on the proposed 11/13/00 CSF, box 9, is 75.6 C (168 F).

CONCLUSIONS:

TRB has reviewed the product chemistry data submitted for Aim 2 EC and has concluded that the submission is not acceptable, for the following *italicized* reasons. FMC must address the following concerns for further consideration:

- *The chemical name on the proposed 11/13/00 CSF, in box 3, must be identical to the one listed on the proposed label, "Aim 2 EC." The product name on the proposed 11/13/00 CSF is "Carfentrazone-Ethyl 240 EC."*
- *EPA files indicate that the concentration of Carfentrazone-ethyl technical used in Aim 2 EC, listed in column 10, must be corrected to read 90%, not 91%. This is also consistent with the concentration of Carfentrazone-Ethyl listed in the proposed CSF for Aim 2 EW. FMC must adjust the concentration of Carfentrazone-ethyl in columns 13a, 13b, 14a, and 14b, of the proposed CSF.*
- *All components in the formulation, column 10 of the proposed CSF (specifically the alternate surfactant), must be used in the formulation of the product, a nominal concentration or upper limit of 0 is not unacceptable. (See Confidential Appendix)*
- *The statement in the proposed CSF, in column 10, explaining that the ... "surfactant is sometimes added to improve leaf coating" is not appropriate to the CSF and must be removed.*
- *The statement that the "limit of surfactants were calculated to be +/-10% to allow for an alternative formulation using..." must be removed from column 10 of the proposed CSF.*
- *Alternative formulations (containing a different type of surfactant, as listed in column 10) must be submitted separately. (See Confidential Appendix)*
- *The complete supplier name and street address is required in box 11 of the CSF, for all components in the formulation, as specified in the directions for completion of the CSF.*

- The EPA Reg. No. of the Carfentrazone-ethyl ai (Reg. No. 279-3181) is required in box 12 of the CSF.
- The amounts of each component in the formulation must be given in column 13(a) of the proposed CSF, as specified in the instructions on form 8570-4.
- The percentage by weight of Carfentrazone-Ethyl ai in box 13b, is incorrectly based on a concentration of 91% technical for Carfentrazone-Ethyl, Reg. No. 279-3181 and must be calculated on the basis of the true, 90% concentration for Carfentrazone-Ethyl.
- The correct nominal concentration of Carfentrazone-Ethyl is 22.1% = $[(0.90 \text{ purity of Carfentrazone-Ethyl}) \times (24.58\% \text{ by weight Carfentrazone-Ethyl in box 13b})]$, NOT 22.36% as stated on the proposed 11/13/00 CSF.
- The proposed 11/13/00 CSF does not comply with PR Notice 91-2 because the nominal concentration of the Carentrazone-Ethyl ai, in column 13b, does not agree with the label claim on either the proposed 11/13/00 or 4/20/01 labels.
- No component of the formulation may contain a nominal concentration of zero. (specifically the alternate surfactant listed in column 13b) (See Confidential Appendix)
- The lower certified limit of the CSF, in column 14, must always be lower than the upper certified limit, for any given component (specifically the alternate surfactant). (See Confidential Appendix)
- The stated label concentration must read 22.1% Carfentrazone-Ethyl, the nominal concentration of Carfentrazone-Ethyl, not 24.6% Carfentrazone-Ethyl (the % by weight given in box 13b of the proposed 11/13/00 CSF).
- The statement underneath the ingredient statement of the proposed label for Aim 2 EC, "Contains 24.6% WW of active ingredient per pound of product" is incorrect and must be eliminated.
- The label for Aim 2 EC and Aim 2 EW should contain the warning "Contains Petroleum Distillates."
- The Physical/Chemical Hazards statement on the proposed 1/23/01 label must read, "FLAMMABLE." as well as and then followed by the statement "Do not use or store near heat or open flame."
- Data corresponding to guideline reference 830.155 (chemical identity) are still required. The data submitted corresponding to the guideline reference 830.1550(Product Identity)and 830.1750 (Certified limits) do not satisfy the data requirements of 40CFR§158.155 and 158.175 respectively, since some of the

inert ingredients used in the formulation are not cleared by the Agency. (See Confidential Appendix)

- *Trade name, CAS No., complete chemical composition and percentages of each component of the inert ingredients not cleared by the Agency, must be provided.*
- *Because the proposed uses of Aim 2 EC and Aim 2 EW include food and feed uses, the inerts listed in the Confidential Appendix must be cleared for use in foods and feeds. (See Confidential Appendix)*
- *Data submitted corresponding to the guideline reference 830.160 (Beginning Materials) are adequate.*
- *Data submitted corresponding to the guideline reference 830.165 (Description of formulation process) and 830.167 (Discussion on the formation of impurities) satisfy the data requirements of 40CFR158.165 and 158.167, respectively.*
- *Data submitted corresponding to the guideline reference 830.175 (Certified Limits) are not satisfied.*
- *Data submitted corresponding to the guideline reference 830.180 (Enforcement of analytical method) satisfy the data requirements of 40CFR§158.180.*
- *Submittal of samples, guideline reference 830.190, is not required, at this time.*
- *Adequate data was submitted (or was not required) to satisfy the following 40CFR§158.190 guideline requirements:*
 - *Physical state(830.6303),*
 - *Oxidation/Reduction (830.6314),*
 - *Flammability(830.6315),*
 - *Miscibility(830.6319),*
 - *Dielectric breakdown voltage(830.6321)*
 - *pH(830.7000),*
 - *Viscosity (830.7100),*
 - *Density(830.7300),*
- *Additional data are needed to satisfy the following 40CFR§158.190 data requirements:*
 - *Explosibility (830.6316),*
- *The following 40CFR§158.190 data are required but underway:*
 - *Storage stability (830.6317) and corrosion characteristics(830.6320),*
- *FMC must specify all of the types of containers to be used for storage, so that the appropriate Storage and Disposal language may be determined. FMC must confirm that the containers to be used are all plastic.*

- *Because the term "Plastic containers:" is included in the "Container Disposal" portion of the "Storage and Disposal" Section of the proposed 1/23/01 label, it is likely that the containers all plastic. If so (FMC must confirm this fact), the "Storage and Disposal" Section of the proposed 1/23/01 label must be revised to read as follows, in accordance with PR 83-3:*

"Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke."

FMC must delete the initial leading words, "Plastic containers:" before their container disposal statement.

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REG./File Symbol No.: 279-GEUR

PRODUCT NAME: Aim 2EC

COMPANY: FMC Corp Agricultural Products Group

1. Reviewer: Linda L. Kutney
2. Company: FMC Corp Agricultural Products Group
3. Type of Submission: Registration [X] Reregistration [] New [X]
Resubmission [] Amendment [] "ME-TOO" [] Alternate Formulation []
Experimental Use Permit [] Other (Specify) _____
4. If "Me-TOO" Registration, this product is [] is not [] similar or substantially similar to EPA's Reg. No.: _____
If not, comment in Confidential Appendix A on the differences between the registered and the new source where significant

CONFIDENTIAL STATEMENT OF FORMULA

5. Type of formulation and the sources of active ingredients:
 - Non-integrated formulation system.....[X]
 - Are all technical grade active ingredients used registered? • yes [X] • no [], If no, specify _____
 - Integrated formulation system.....[]
6. Clearance of intentionally added ingredients in the formulation for the intended use (indicate in the Confidential Appendix those that are not cleared; the PC Codes should be provided by the chemist on the CSF for those that are cleared):
- 6(a) Formulation intended for food use under 40CFR§180.1001:
 - yes [X] • no []

Cleared under list: • c[] • d[] • e[]

- Some are cleared, others are not [X] Are there any limitations for use as an inert under 40CFR§180.1001?

• yes [] • no [], If yes, specify _____

- 6(b) Formulation intended for non-food use:

• yes [] • no [X] • Some are cleared, others are not []

- 6(c) Clearance by the FDA of certain formulations under 21CFR§170 to 199.

Examples: (a) indirect food additives, such as food contact surface sanitizers; adhesives, coatings, paper and paperboard products that may contact food in packaging or holding; and (b) substances generally recognized as safe (GRAS).

• yes [] • no [X] • Some are cleared, others are not []

If yes, the entire formulation is cleared under 21CFR§_____

7. The density, pH, and flammability values given on the CSF are identical with those of GRN 830.7300(density), 830.7000(pH), and 830.6315(Flammability),

respectively:

- yes [X] • no []

8. The nominal concentrations (NC) of the active ingredients and the upper and lower certified limits (UCL & LCL) are as follows:

Active ingredient(s)	% by weight		
	NC	UCL	LCL
Carfentrazone-Ethyl	22.1	22.8	21.4

9. The calculated NCs, based on the pure active ingredients (PAI), are identical to those on the label:
 • yes [] • no [X]
10. The certified limits are within the standard limits as per 40CFR§158.175 or are adequately explained if different: • yes [] • no [X]

PRODUCT LABEL

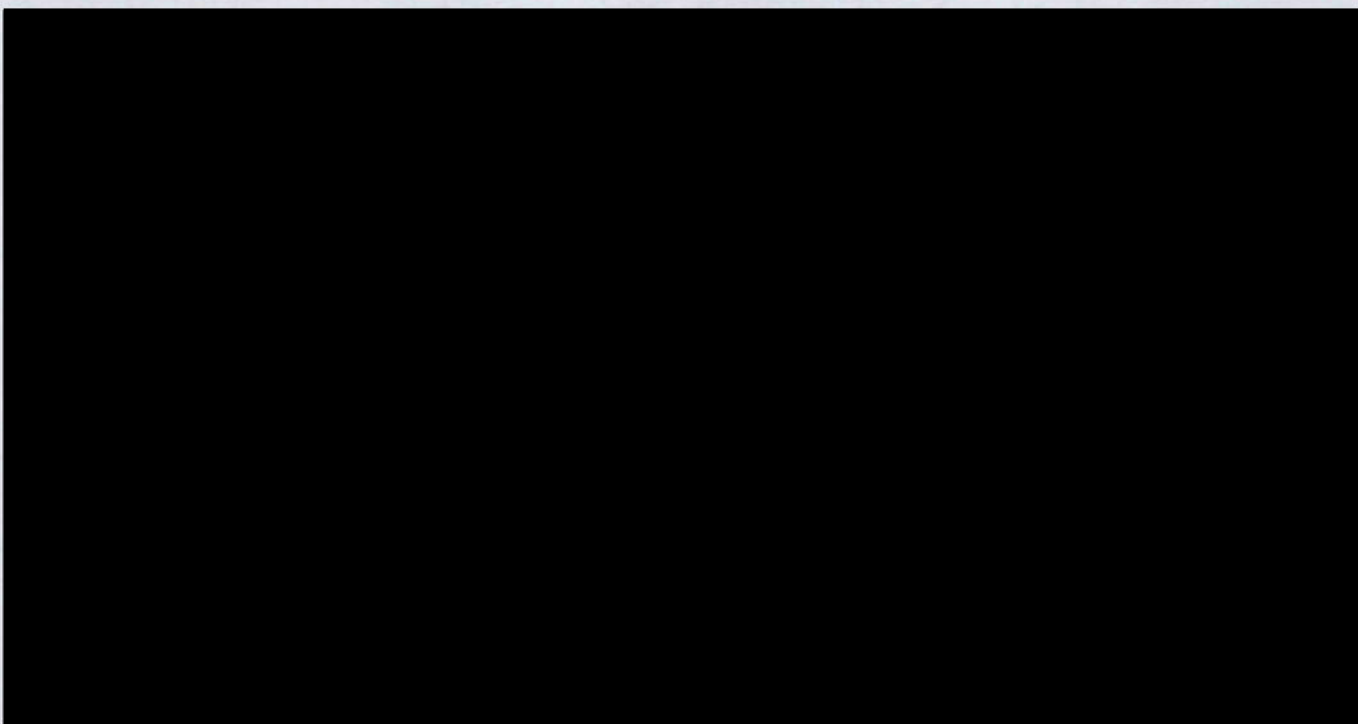
11. The chemical names of the active ingredients on the label are identical to those on the CSF: • yes [] • no [X]
12. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label:
 • yes [] • no [X] • not applicable []
13. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses:
 • yes [] • no [X]

PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B)

14. Chemical IDs/Manufacture/ Analytical Information New Guideline:830.--	Data Required Fulfilled	MRID No.
1550. Chemical Identity(CSF)	No	
1600. Beginning Materials	Yes	453252-01
1620. Formulation Process	Yes	453252-01
1750. Certified Limits (CSF)	No	
1800. Enforcement of Analytical Method (required for integrated products & those of tox. concern)	Yes	453252-01
1900. Submittal of Samples (required for integrated products, those of tox. concern, and for nonintegrated products with interference, etc, method problems)	No	

15. Physical/Chemical Properties New Guideline No. 830.---	<u>Data Required Fulfilled</u>	<u>Value or Qualitat. Descrip.</u>	<u>MRID No.</u>
6303. Physical State	Yes	Yellow- Orange Liquid @ 20 C	453252-01
6314. Oxidation Reduction Reaction	Yes	Does not contain strong oxidizers or reducers	453252-01
6315. Flammability/Flame Extension	Yes	>75.6 C or 168 F	453252-01
6316. Explodability	No	FMC says contains no high energy ai or inert, but is flammable	453252-01

6317. Storage Stability	Required but Underway	Compatible for 1 month, room temperature, in paper and polyethylene	453252-01
6319. Miscibility	Not Required	Not diluted in organic solvents	453252-01
6320. Corrosion Characteristics	Required but Underway	Compatible for 1 month, room temperature, in paper and polyethylene	453252-01
6321. Dielectric Breakdown Voltage	Not Required	Not used around electrical equipment	453252-01
7000. pH	Yes	4.66 @ 21.8 C	453252-01
7100. Viscosity	Yes	8.19 Centistokes at 25 C	453252-01
7300. Density/Bulk Den.	Yes	1.075 g/ml, 8.97 lb/gal at 20 C (68 F)	453252-01

CONFIDENTIAL APPENDIX

****Inert ingredient information may be entitled to confidential treatment****

NOTE TO THE PM:

Please include the new, revised 4/20/01 label in the JACKET.